

EXHIBIT 74

From: Al Van Duren
To: Linda Johnsen
CC: holdene@gtlaw.com
Sent: 8/20/2015 9:55:42 PM
Subject: RE: Supporting Data
Attachments: Anesth Analg 2011; 113 1416-21.pdf; Hall presentation 1991.pdf; Memarzadeh 2010 LTE JHI.pdf; MHRA August 7, 2008.pdf; MHRA July 26, 2010.pdf; MHRA June 22, 2010.pdf; Olmstead Poster 2010.pdf; References.docx

Attorney Client
Communication



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From: Linda Johnsen
Sent: Wednesday, August 19, 2015 4:44 PM
To: Al Van Duren
Cc: Dave Westlin
Subject: Supporting Data

Al,
Thank you so much.

To be **brief**:

- 1) Received a number of complaints alleging infections.
- 2) Within the MDR reporting requirements you are exempt from reporting (**Bold Emphasis Mine**) based on CFR803.20 (C) (2)

(c) What kind of information reasonably suggests that a reportable event has occurred?

(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(2) If you are a user facility, importer, or manufacturer, **y ou do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury**, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. **Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers.** You must keep in your MDR event files (described in 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

- 3) I have attached a piece provided to me from Dave Westlin that you may want to refer to.

In summary,

Looking for a qualified person article, study or letter that would support decision as noted above.

In addition references (information) that could be referred to.

Thank you for your support.

Linda



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References.docx